UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/243,342	05/16/94	BUCALA R	7815008

18N2/0307

PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER	
MARSCHEL,A	
ART UNIT	**PAPER NUMBER**
1809	

DATE MAILED: 03/07/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/243,342	Bucala et al.
Examiner	**Group Art Unit**
Ardin Marschel	1809

☒ Responsive to communication(s) filed on 1-23-97.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 63, 64, 80-82, and 84-90 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 63, 64, 80-82, and 84-90 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892 ✓

☒ Information Disclosure Statement(s), PTO-1449, ~~Paper No(s).~~ 3 sheets ✓

☒ Interview Summary, PTO-413 ✓

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 ✓

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1809.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application. It is noted that a priority claim is present in the Declaration but not reflected in said first sentence.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63 and 84-90 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to MIF gene expression inhibitors as listed in claim 64. Other agents that would potentially go beyond those of claim 64 have received no guidance in the disclosure as filed as to what they may be. Thus, finding any agents beyond those in claim 64 is unpredictable and at best an invitation to experiment. Such an invitation to experiment is undue experimentation. It is noted that the specification cites antibodies etc. that may be MIF protein inhibitors but these are expected to be effective

only after the gene has expressed the MIF protein. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 63, 64, 80-82, and 84-90 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63, for example, is vague and indefinite in that lines 2-3 cite "an individual" without defining what selection criteria is intended for that "individual". There is no claim wording, for example, that the individual must be subject to cytokine-mediated toxicity. This may be implied but implied limitations fall short of clear and concise limitations.

Claim 63 etc. are directed to administration of an agent of various types but the claims do not include any limitation directed to what is not inhibited. Thus, non-specific as well as specific gene expression inhibitors may be reasonably viewed as being within the scope of the claims. This, however, is confusing since the claims also cite "cytokine-mediated toxicity". Do applicants intend generic inhibitors to be included within the metes and bounds of the claims or is there an intention to utilize an agent that only inhibits MIF gene expression. If so, the claims do not presently state this in any clear fashion.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this

Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 63 and 84-90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over pages 54-57 of Principles of Drug Action.

On page 54, third full paragraph, antinomycin D is cited as being an antibiotic. In the bridging sentence between pages 54 and 55 antinomycin D is described as blocking transcription in mammalian as well as bacterial cells. Such a generic block of transcription would inhibit any gene expression including MIF gene expression when administered to an individual as an antibiotic. This administration is motivated and suggested in the reference by referring to actinomycin D as an antibiotic. Antibiotics are drugs that are administered as needed to

patients. Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to administer actinomycin D which generically would inhibit gene expression suggesting that MIF gene expression would be inhibited as well thus resulting in the practice of the instant invention.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-7401 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

March 3, 1997

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER
GROUP 1800